

Structured Product Labeling (SPL) OTC Sub-team Teleconference
November 16, 2009, 1:00 – 2:00 pm ET
Call Summary

I. Call Attendees (based on emails received)

Attendance is based on email replies received. Call participants who are not listed below but were on the call (or you are listed and were not on the call) should notify Marcia Howard.

-  Paule Belony, The Belony Group LLC
-  Cheryl Blik, Teva Pharmaceuticals, Inc.
-  Gail Burke, Procter & Gamble
-  Lisa Fields, Blistex, Inc.
-  Chris Guay, Procter & Gamble
-  Maureen Kapustynski, Cadbury
-  Mike Koenig, FDA
-  Juris Lazdins, Novartis Consumer Health, Inc.
-  Carolyn Lindsay, Cardinal Health
-  Paula Markert, GlaxoSmithKline (sub-team co-leader)
-  Kathryn Moreng, Bayer Consumer HealthCare
-  Alison Rago, Intagras
-  Janet Riffitts, McNeil Consumer Healthcare
-  Eva Rivera, Glemser Technologies Corporation
-  Gary Saner, Reed Technology & Information Services, Inc.
-  David Schilling, Chattem, Inc.
-  Howard Shatz, Data Conversion Laboratory, Inc.
-  Carl Strotz, Pfizer Consumer Healthcare
-  Angela Urso, MedImmune
-  Karen Vescovi, Church & Dwight Co., Inc.
-  JoAnn Witek, Consultant
-  Marcia Howard, CHPA staff (sub-team liaison)

II. Next Standing Teleconference: November 30, 2009, 1:00pm ET

III. FDA Data Council Information (*Not All-inclusive*)

A. SPL Terminology Update – UNIIs (Updated November 12, 2009) *added after agenda was sent*

1. Include an updated version of the SPL Starter Package with version 1.03 of the listing SPL Xforms:

<http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/ucml89651.htm>.

2. Add a hyperlink to the HL7 SPL Working Group's SPL web page (under "Resources for You" heading):

<http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm>

B. SPL Terminology Update – UNIIs (Updated November 7, 2009):

1. UNII update -

<http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/ucml62523.htm>

2. Updated terminology XML Files (include updated UNII XML file) -

<http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/ucml69455.htm>

IV. Upcoming SPL Educational Forums/Information (*For Your Information*)

FDA SPL R4 Training Sessions – Please visit website for updated information regarding training courses.

<http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/ucml55705.htm>

- A. **FDA Training Sessions:** Monday webinars at 10:00 am ET and Q&A sessions at 11:30 am ET (same for both; cancelled for Federal holidays)
Telephone number: 1-866-775-9435
Participant pass code: 5753366
Please dial-in early as there are a limited number of ports and when they are exhausted, no one else will be able to connect to the conferences.

FDA has released a series of e-Training Books and Cards that are available on the SPL Wiki page as another SPL resource to industry.
(<http://spl-work-group.wikispaces.com/>)

- B. **SPL Process Communication Forum (Process Team):** Alternating Wednesdays 1:00 - 2:30 pm ET (unless cancelled; opposite to ERDL calls)
Telephone number: 877-423-2663
PIN#: 558089
Please email Process Team co-leaders Terry Brunone (Theresa.M.Brunone@gsk.com) or Mary Beth Wilusz (mary_beth_wilusz@merck.com) if you want to get the email information.
- C. **SPL ERDL Sub-team calls:** Alternating Wednesdays at 1:00 pm ET (unless cancelled)
Telephone number: 866-217-3840
Conference Code: 4286445422
Please email sub-team leader Michael Fahmy if you want to get the email information (michael.fahmy@bms.com).
- D. **SPL Generics Sub-team calls:** First Tuesdays of each month at 1:00 pm ET (unless cancelled)
Telephone number: 866-618-6746 (toll-free)
201-527-2133 (international/caller paid)
Access Code: 8957842
Please email sub-team leader Virginia Hogan if you want to get the email information (Virginia.Hogan@tevausa.com).
- E. **Others – *Note: although members of the various SPL sub-teams may be involved in the following programs, no endorsement or recommendation is implied***
1. CBI's Forum on [FDA's Structured Product Labeling \(SPL R4\)](#), December 8-9, 2009, in Washington, DC
 2. DIA Webinar: [Preparation of Electronic Drug Establishment Registration and Drug Product Listing \(eDRL\) Submissions in SPL format: What You Need to Know](#). (December 8, 2009)

V. Discussion Topics

A. SPL Content of Labeling Draft Guidance

<http://edocket.access.gpo.gov/2009/pdf/E9-25940.pdf> (Notice)

<http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM072392.pdf> (Draft Guidance)

The SPL Leadership Team agreed to issue a letter of appreciation to FDA for their ongoing commitment to provide educational information to industry on SPL-related matters. Sub-team members were asked to review the draft before the November 30th call to determine if collective comments should be submitted about the content of the draft guidance. If no response by the next SPL OTC sub-team call, we will assume that companies will provide comments to the FDA via the docket. Regardless of the decision of the SPL Leadership Team, SPL OTC sub-team, and other SPL working groups, companies are encouraged to submit comments as deemed necessary.

B. Import Issues

Sub-team members were asked to complete the online survey by Tuesday, November 17th to provide feedback on import issues. The survey can be accessed at

http://www.surveymonkey.com/s.aspx?sm=GClpsYBsX9GBwJNv1MkKjQ_3d_3d. The survey will be open until Tuesday, November 17, 2009, COB ET

to allow time to analyze the results before the call with FDA staff (link originally sent 11/9/09; resent 11/16/09). Key information requested includes:

- Type of product/s involved (OTC monograph, OTC ANDA/NDA, Rx, other)
- Port of entry/import staff/district involved
- If related to SPL e-submissions
- Business impact
- Frequency/patterns
- Any other details that would be helpful to illustrate the problem
- Recommendations to correct or solve the matter

Several companies have reported issues with imported products being delayed at the border because paper documents for product listing no longer exist. FDA is conducting training as quickly as possible but there may be some staff that is still not aware of SPL. The purpose of the call

with FDA staff, including Lonnie Smith, is to brainstorm for ideas beyond continued training in hopes of resolving these issues. The results, which will be blinded, will also be presented at the next sub-team call for further discussion and idea generation.

Lonnie Smith has graciously offered to assist with import issues as much as possible but a request will be made to speak to FDA management about the problems. Note that Lonnie/FDA can only help if the listing process has been completed satisfactorily; they cannot provide assistance if the SPL submission has not been properly done.

FDA has suggested the following steps to help minimize the chance of delayed importation of products.

Tips provided by Terry Brunone and available on the SPL Wiki page:

Here a few tips. With respect to import issues, if you send an email to the SPL account (SPL@fda.hhs.gov), please indicate in the subject header (in no specific order):

1. If this is an urgent issue – please mark urgent only when it really is...if you anticipate an import issue, please send FDA a message as early as possible so they will have adequate time to research the issue and reply to your message
2. That it is related to an import issue
3. The specific product/s for which you are requesting assistance

In the body of the message, provide any additional details that will help FDA research the issue as quickly as possible. If there are problems at the border, include the name and number of the Port of Entry in communications and/or district office to the SPL@fda.hhs.gov

FDA is doing all it can to get the import staff trained but until this occurs (and there are a lot of people that must be made aware of the changes so it won't happen immediately), they recognize that companies may need their assistance to resolve some of the import questions that arise. Hopefully these tips will help.

from: <http://spl-work-group.wikispaces.com/Import+Q-and-A> and
<http://spl-work-group.wikispaces.com/Questions+from+August+29+Process+Call>

VI. Updates – Requesting UNIs for Simethicone – see questions below

One company has submitted information regarding simethicone. Other companies are still consulting with their staff chemists to address the questions so the item will be tabled for two weeks. Interested sub-team members should consult with their internal colleagues and send their responses to Marcia Howard by November 30, 2009.

VII. Other – API Manufacturer Product Listing

Some SPL OTC sub-team members reported experiencing reluctance by active pharmaceutical ingredient (API) manufacturers to list their ingredients. This could pose a problem, especially for imported APIs, if e-listing becomes required and not just recommended in the guidance document. It is possible that the API manufacturers are unaware of SPL or are just reluctant to follow a recommendation. Marcia Howard will ask the item to be placed on the agenda for the SPL Process Team and Leadership Team calls to see how this issue might be best addressed.

MDH/11-16-09

SPL OTC Sub-team 16 November 2009 111609.doc
Last Revised: November 17, 2009 Sent: November 17, 2009

Message received from SPL OTC sub-team member from FDA (identifying information removed):

Requesting UNII for Simethicone

You requested for one UNII to be assigned to simethicone instead of the two substances. It is the FDA Substance Registration System team's position that simethicone can always be listed as a mixture of a given type dimethicone and silicon dioxide.

Due to the amount of recent requests for assignment of a UNII for simethicone by several companies, before we can even consider the assignment a UNII to this term we have some questions.

Note that these are not to be considered as regulatory questions and are only posed as questions due to your request for the assignment of a term to be utilized in the product data elements section of a listing SPL document. You are not obligated in any way to answer these questions and should you opt to reply, your responses will not have any bearing on the approval (if applicable) or listing of your drug.

1. From some of the formulation sheets we have received with requests for an assignment of a UNII for simethicone, it appears that the potency listing is actually based on the amount of dimethicone. Do all the manufactures use a USP grade of simethicone where the amount of silicon dioxide is limited to between 4 and 7%? For example when you list 125 mg/tablet does this mean there will always be between 4 and 9 mg of silicon dioxide and 125 mg of dimethicone or does it mean 125 mg of the mixture dimethicone + silicon dioxide? If there is more than 7% silicon dioxide in a table do you list silicon dioxide as a separate ingredient?
2. What type of dimethicone is typically used? There are a variety of types of Dimethicone each of which differ by molecular weight and would get a separate UNII.
3. Which dimethicones are typically used in the manufacturing of simethicone for pharmaceutical grade material? Is this something that is always controlled? The literature indicates that dimethicones between 20 and 3000 CS are typically used. Unfortunately the USP monograph does the specify the need for the label to indicate the type of dimethicone used.
4. Do manufacturers always use the same type of dimethicone in a given product? The type of dimethicone may influence the performance of the product.